IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

SHIRE DEVELOPMENT LLC, SHIRE CANADA INC., and SHIRE INTERNATIONAL LICENSING B.V., Plaintiffs, v. INVAGEN PHARMACEUTICALS, INC., Defendant.	C.A. No. 14-cv-7263

COMPLAINT

Plaintiffs Shire Development LLC, Shire Canada Inc., and Shire International Licensing B.V. (collectively "Shire" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant InvaGen Pharmaceuticals, Inc. ("InvaGen") herein allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 5,968,976 ("the '976 patent"), 7,381,428 ("the '428 patent"), and 7,465,465 ("the '465 patent"), attached hereto as Exhibits A, B, and C, respectively.

THE PARTIES

2. Plaintiff Shire Development LLC is a limited-liability company organized and existing under the laws of Delaware and has a principal place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

3. Plaintiff Shire Canada Inc. is a corporation organized and existing under the laws of Canada and has a principal place of business at 2250, boul. Alfred-Nobel, bureau 500, Ville St-Laurent, QC H4S 2C9, Canada.

4. Plaintiff Shire International Licensing B.V. is a corporation organized and existing under the laws of the Netherlands and has a principal place of business at Strawinskylaan 659, 1077 XX Amsterdam, Noord-Holland, The Netherlands.

5. Upon information and belief, Defendant InvaGen is a corporation organized and existing under the laws of New York and has a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788.

6. Upon information and belief, InvaGen is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the State of New York.

JURISDICTION AND VENUE

7. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over InvaGen because, *inter alia*: (i) InvaGen is incorporated in New York; and (ii) its principal place of business is in New York.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

10. Shire Development LLC owns New Drug Application ("NDA") No. 21-468, for lanthanum carbonate chewable tablets, which was approved for 500 mg tablets on October 26, 2004, and for 750 mg and 1000 mg tablets on November 23, 2005. Shire markets these tablets under the name Fosrenol®.

11. Fosrenol is indicated to reduce serum phosphate in patients with end stage renal disease.

12. The '976 patent, entitled "Pharmaceutical Composition Containing Selected Lanthanum Carbonate Hydrates," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 19, 1999. Shire International Licensing B.V. owns all rights, title, and interest in the '976 patent.

13. The '428 patent, entitled "Stabilized Lanthanum Carbonate Compositions," was duly and legally issued by the USPTO on June 3, 2008. Shire International Licensing B.V. owns all rights, title, and interest in the '428 patent.

14. The '465 patent, entitled "Pharmaceutical Formulation Comprising Lanthanum Compounds," was duly and legally issued by the USPTO on December 16, 2008. Shire Canada Inc. owns all rights, title, and interest in the '465 patent.

15. Pursuant to 21 U.S.C. § 355(b)(1), the '976, '428, and '465 patents are listed in the United States Food and Drug Administration's ("FDA") publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering Fosrenol.

16. InvaGen prepared, submitted, and filed an Abbreviated New Drug Application ("ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval from the FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of lanthanum carbonate ("ANDA No. 206868"). InvaGen included a "paragraph IV" certification seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of lanthanum carbonate (equivalent to

500 mg, 750 mg, and 1000 mg lanthanum) chewable tablets ("InvaGen's ANDA Products") before the expiration of the '976, '428, and '465 patents.

17. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)-(ii).

18. Shire received a letter dated October 30, 2014 that was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, 21 U.S.C. § 505(j)(2)(B)(ii), regarding InvaGen's ANDA Products and the '976, '428, and '465 patents (the "October 30 Notice Letter"). Contrary to the statute and its attendant regulations, the October 30 Notice Letter fails to "include a detailed statement of the factual and legal basis" for InvaGen's noninfringement contentions and instead only provides conclusory statements that InvaGen's ANDA Products do not meet certain identified claim limitations.

19. The October 30 Notice Letter does not make any noninfringement contentions unique to claims 2-6 or 8-10 of the '976 patent; claims 2-3 or 8-9 of the '428 patent; or claims 5-8 or 11-12 of the '465 patent.

20. The October 30 Notice Letter is silent as to any invalidity or unenforceability contentions with respect to any claim of the '976, '428, or '465 patents and fails to meet the requirements mandating that such letter provide full and detailed grounds to support any allegations of invalidity or unenforceability.

21. The October 30 Notice Letter was signed by Robert S. Silver of the law firm Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.

22. The October 30 Notice Letter included an Offer of Confidential Access ("OCA") purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Plaintiffs objected to certain provisions of InvaGen's OCA as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III). By way of example only, InvaGen's OCA contains a patent-prosecution bar and a bar on conducting work before the FDA, even though InvaGen has provided no facts to show that there is good cause to impose such bars.

COUNT I
(Infringement of the '976 Patent)

23. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

24. Upon information and belief, InvaGen's submission of ANDA No. 206868 to the FDA is for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products—products (1) that are claimed in the '976 patent and (2) whose use is claimed in the '976 patent—before the expiration of the '976 patent.

25. Upon information and belief, InvaGen included in ANDA No. 206868 a paragraph IV certification to the '976 patent to obtain approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products before the expiration of the '976 patent.

26. Upon information and belief, InvaGen will commercially manufacture, use, sell, offer for sale, and/or import its ANDA Products upon, or in anticipation of, FDA approval.

27. The submission and filing of ANDA No. 206868 with a paragraph IV certification to the '976 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products before the expiration of the '976 patent is an act of infringement by InvaGen—literally and/or under the doctrine of equivalents—of one or more claims of the '976 patent under 35 U.S.C. § 271(e)(2).

28. As of the date of the October 30 Notice Letter, InvaGen was aware of the existence of the '976 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the '976 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

COUNT II
(Infringement of the '428 Patent)

29. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

30. Upon information and belief, InvaGen's submission of ANDA No. 206868 to the FDA is for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products—products (1) that are claimed in the '428 patent and (2) whose use is claimed in the '428 patent—before the expiration of the '428 patent.

31. Upon information and belief, InvaGen included in ANDA No. 206868 a paragraph IV certification to the '428 patent to obtain approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products before the expiration of the '428 patent.

32. Upon information and belief, InvaGen will commercially manufacture, use, sell, offer for sale, and/or import InvaGen's ANDA Products upon, or in anticipation of, FDA approval.

33. The submission and filing of ANDA No. 206868 with a paragraph IV certification to the '428 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products before the expiration of the '428 patent is an act of infringement by InvaGen—literally and/or under the doctrine of equivalents—of one or more claims of the '428 patent under 35 U.S.C. § 271(e)(2).

34. As of the date of the October 30 Notice Letter, InvaGen was aware of the existence of the '428 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the '428 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

COUNT III
(Infringement of the '465 Patent)

35. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

36. Upon information and belief, InvaGen's submission of ANDA No. 206868 to the FDA is for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products—products that are claimed in the '465 patent—before the expiration of the '465 patent.

37. Upon information and belief, InvaGen included in ANDA No. 206868 a paragraph IV certification to the '465 patent to obtain approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products before the expiration of the '465 patent.

38. Upon information and belief, InvaGen will commercially manufacture, use, sell, offer for sale, and/or import InvaGen's ANDA Products upon, or in anticipation of, FDA approval.

39. The submission and filing of ANDA No. 206868 with a paragraph IV certification to the '465 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products before the expiration of the '465 patent is an act of infringement by InvaGen—literally and/or under the doctrine of equivalents—of one or more claims of the '465 patent under 35 U.S.C. § 271(e)(2).

40. As of the date of the October 30 Notice Letter, InvaGen was aware of the existence of the '465 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the '465 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 206868 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products—products (1) that are claimed in the '976 patent and (2) whose use is claimed in the '976 patent—before the expiration of the '976 patent—constitutes an act of infringement of the '976 patent by InvaGen;

B. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), the effective date of any approval of InvaGen's ANDA Products shall be no earlier than the date on which the '976 patent expires, including any regulatory extensions;

C. Injunctive relief pursuant to 35 U.S.C. §§ 271(e)(4)(B) for InvaGen's infringement of the '976 patent;

D. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 206868 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products—products (1) that are claimed in the '428 patent and (2) whose use is claimed in the '428 patent—before the expiration of the '428 patent—constitutes an act of infringement of the '428 patent by InvaGen;

E. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), the effective date of any approval of InvaGen's ANDA Products shall be no earlier than the date on which the '428 patent expires, including any regulatory extensions;

F. Injunctive relief pursuant to 35 U.S.C. §§ 271(e)(4)(B) for InvaGen's infringement of the '428 patent;

G. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 206868 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of InvaGen's ANDA Products—products that are claimed in the '465 patent—before the expiration of the '465 patent—constitutes an act of infringement of the '465 patent by InvaGen;

H. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), the effective date of any approval of InvaGen's ANDA Products shall be no earlier than the date on which the '465 patent expires, including any regulatory extensions;

I. Injunctive relief pursuant to 35 U.S.C. §§ 271(e)(4)(B) for InvaGen's infringement of the '465 patent;

J. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys' fees;

K. A Judgment awarding Plaintiffs their costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

L. Such other and further relief as this Court may deem just and proper.

Dated: December 12, 2014

Respectfully submitted,

By: s/ Edgar H. Haug

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